103D CONGRESS
1ST SESSION

S. 222

To require the Commissioner of Food and Drugs to collect information regarding the drug RU–486 and review the information to determine whether to approve RU–486 for marketing as a new drug, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 27 (legislative day, JANUARY 5), 1993

Mr. WELLSTONE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To require the Commissioner of Food and Drugs to collect information regarding the drug RU–486 and review the information to determine whether to approve RU–486 for marketing as a new drug, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Antiprogestin Testing Act of 1993''.

SEC. 2. INFORMATION.

(a) COLLECTION.—

(1) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') shall, to the extent possible, collect information with respect to the drug RU–486, also known as Mifeprestone, including samples and specimens, that is required to be submitted by an applicant for approval of a new drug, as described in section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(2) USES OF DRUG.—The Commissioner shall collect such information regarding—

(A) use of the drug as an abortifacient or contraceptive; and

(B) use of the drug for the treatment of cancer, brain tumors, Cushings syndrome, or other serious or life-threatening diseases.

(b) CONSIDERATION.—The Commissioner shall consider the information collected under subsection (a) with respect to the drug to be an application, submitted by the manufacturer of the drug, for approval of the drug for each of the uses described in subsection (a)(2).

(c) APPROVAL DECISION.—

(1) IN GENERAL.—The Commissioner shall review the information collected under subsection (a) as if the information comprised such an application.

The Commissioner shall issue an order approving, or refusing to approve, the application with respect to each of the uses in accordance with subsections (c) and (d) of section 505 of such Act.

(2) REFUSAL TO APPROVE DUE TO INSUFFICIENT TESTS, INFORMATION, OR EVIDENCE.—

(A) NOTIFICATION OF DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.—The Commissioner shall notify the Director of the National Institutes of Health (referred to in this section as the ''Director'') if the Commissioner issues an order refusing to approve the application because of—

(i) the lack of inclusion of adequate tests in the investigation of the drug, as described in section 505(d)(1) of such Act;

(ii) insufficient information, as described in section 505(d)(4) of such Act; or

(iii) a lack of substantial evidence, as described in section 505(d)(5) of such Act.

(B) INFORMATION.—On so notifying the Director, the Commissioner shall submit to the Director all information relevant to the decision of the Commissioner to issue such order. Such information shall include a description of the

tests that were not included in the investigation, or a description of the information or evidence that was not submitted with the application.

(3) REPORT.—The Commissioner shall prepare, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report concerning any order issued under paragraph (1).

(d) RESEARCH.—

(1) IN GENERAL.—If the Commissioner issues an order refusing to approve the application, the Director shall expeditiously conduct or support research (including clinical trials) on RU–486, in order to conduct the tests, or develop the information or evidence, described in subsection (c)(2)(B).

(2) INSTITUTIONAL REVIEW BOARDS AND PEER REVIEW.—Research conducted or supported under paragraph (1) shall be subject to sections 491 and 492 of the Public Health Service Act (42 U.S.C. 289 and 289a).

(3) RESULTS.—The Director shall submit the results of the research to the Commissioner. The Commissioner shall consider the results, along with

the information collected under subsection (a) with respect to the drug, to be information submitted by the manufacturer of the drug as described in subsection (b), and shall review, and issue an order approving or refusing to approve, the application for the drug, in accordance with subsection (c).

(e) REPORT.—The Secretary of Health and Human Services shall prepare, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report on the status of research conducted or supported under subsection (d) within 6 months of the date on which the Commissioner provides notification under subsection (c)(2)(A), and every 6 months thereafter until the research is completed.

SEC. 3. FEES AND COSTS.

If the Commissioner issues an order approving an application with respect to the drug RU–486 for a use described in section 2(a)(2), any person who introduces the drug into interstate commerce or delivers the drug for introduction into interstate commerce for such use shall reimburse—

(1) the Food and Drug Administration for—

(A) the amount indicated in the fee schedule set forth in section 736 of the Federal Food, Drug, and Cosmetic Act; and

(B) the amount of the costs incurred by the Commissioner in complying with section 2(a); and

(2) the National Institutes of Health for the amount of any costs incurred by the Director in complying with section 2(d).

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